

REMARKS

This Amendment After Final is submitted in response to the Office Action mailed on December 11, 2007. With this Amendment After Final, claims 1, 15, 26 and 37 are amended.

Claim Rejections – 35 U.S.C. § 103

In the Office Action, claims 1-48 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Maahs (U.S. 5,846,260) in view of Tanner et al. (U.S. 6,635,066) and further in view of Corcoran et al. (U.S. 6,656,206). Specifically, the Examiner stated that Maahs discloses an occlusion device (70) comprising a plurality of ribs (72) extending from the proximal end of the center post (62); and a foam sheet (82) attached to the plurality of ribs (72,75) and that it would have been an “obvious matter of design choice to make a diameter of ribs (72) near the proximal end of the center post (62) greater than a diameter of the ribs (72) near the distal end of the center post”.

With this Amendment After Final, independent claims 1, 15, 26 and 37 have been amended to clarify the overall function of the device of the present invention. Specifically, independent claim 1 has been amended to clarify that the present invention is an occlusion device for occluding a left atrial appendage, which comprises a center post having a proximal end and a distal end, a plurality of ribs extending radially outward from the proximal end of the center post to the distal end of the center post to form a frame, and a PVA foam sheet attached to the ribs. A diameter of the frame near the proximal end of the center post is greater than a diameter of the frame near the distal end of the center post and is shaped to securely fit within a left atrial appendage. The PVA foam sheet forms a barrier to prevent blood from entering or exiting the left atrial appendage.

Similarly, independent claims 15, 26 and 37 have also been amended to clarify that the sheet forms a barrier to prevent blood from entering or exiting the left atrial appendage.

Therefore, the present invention is an occlusion device for sealing a left atrial appendage (LAA), which is a small cavity opening into the left atrium of the heart. Studies indicate that elimination of the LLA, through occlusion or closure, may prevent thrombi from forming in the

LLA and thus may reduce the incidence of strokes in patients diagnosed with atrial fibrillation. Pg. 3, ll. 1-3. The LLA is shaped like a small thumb which terminates as it tapers away from the opening. Pg. 2, ll. 7-11. Although the shape of the device may vary somewhat, the device is preferably shaped to fit into the LAA so that the device remains securely deployed and forms a barrier to prevent blood from entering or exiting the LAA. As a result, the device of the present invention must be configured to perform this specific task. Therefore, the device of the present invention must be able to effectively block blood flow from shunting through the LAA.

In contrast, the device described in Maahs is a modular blood filter device for temporary placement in a blood vessel to capture embolic material dislodged during a surgical procedure. Col. 1, ll. 4-6. As a result, in addition to having a different structure and shape than the device of the present invention, the Maahs device also includes “filter mesh attached to the expansion frame” as opposed to a foam sheet. Col. 2, ll. 36-38. Filter mesh is used because when the device is deployed within a blood vessel, the filter mesh opens “substantially across the vessel and captur[es] any embolic material traveling therethrough”. Col. 7, ll. 37-39. In this way, the Maahs device is able to trap embolic material “without substantially impairing blood flow through the vessel”. Col. 3, ll. 60-61. Therefore, the Maahs device is configured to perform a very different task than the device of the present invention in that the Maahs device filters blood flow while the device of the present invention prevents blood flow by forming a barrier.

Since Maahs performs a different function than the device of the present invention, it would have not been obvious to redesign the materials used or dimensions of the device in order to perform a completely new, and somewhat conflicting, function. In addition, while Maahs discloses use of a self-expanding foam (82) to fill a notch of strut (75), Maahs does not teach the use of foam to form the mesh filter material. In fact, Maahs more accurately teaches away from the use of a foam sheet in place of the mesh filter material described because Maahs emphasizes the need to prevent impairment of the flow of blood through the filter in which it is deployed. As described with respect to the present invention, use of a foam sheet in conjunction with frame results in a device which

upon deployment forms a barrier to effectively prevents the flow of blood from entering and exiting the LAA.

To render an invention obvious, the cited references must disclose all of the claims limitations or teach or suggest all of the claim limitations. As described above, Maahs does not disclose, teach or suggest all of the limitations of the independent claims. Furthermore, neither Tanner nor Corcoran supplies the missing teachings. If an independent claim is non obvious, then any of the claims depending therefrom are likewise nonobvious. *See* MPEP § 2143.03 (*citing* In re Fine, 5. U.S.P.Q2d (BNA) 1596 (Fed. Cir. 1998)). Therefore, claims 1-48 are not obvious, and the rejection under 35 U.S.C. § 103(a) is overcome.

Conclusion

With the above amendments and discussion, the claims 1-10 and 12-48 are in condition for allowance and notice to that effect is requested.

The Commissioner is authorized to charge any additional fees associated with this paper or credit any overpayment to Deposit Account No. 11-0982.

Respectfully submitted,

KINNEY & LANGE, P.A.

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By: 

David R. Fairbairn, Reg. No. 26,047
THE KINNEY & LANGE BUILDING
312 South Third Street
Minneapolis, MN 55415-1002
Telephone: (612) 339-1863
Fax: (612) 339-6580

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